

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Oct 2026

Comparison of paracetamol and ketamine for post-operative pain management in patients undergoing total abdominal hysterectomy

Protocol summary

Summary

The aim of this randomized, double blind clinical trial study was to compare the effects of ketamine and paracetamol for postoperative pain management after total abdominal hysterectomy. After receiving approval from Ethical Committee of Tehran University of Medical Science and written informed consent, we enrolled 80 patients of ASA physical status I-II scheduled for elective total abdominal hysterectomy. Patients with a history of addiction to opiates, known allergy to acetaminophen or ketamine, alcoholism and drug abuse, hepatic disease, seizure and aged below 25 yr and above 65 yr were excluded from the study. Patients were assigned to one of two treatment groups according to a computer-generated list of random numbers. Patients in group I, 40 patients, received 1 gr intravenous acetaminophen (Apotel) intraoperatively until skin closure. whereas those in group II, 40 patients, received intravenous bolus ketamine 0.15 mg/kg after extubation. A patient control analgesia device with 15 cc fentanyl and 85 cc normal saline was used to provide postoperative pain relief. Each ml of solution contained 7.5 mcg of fentanyl. The solution infused continuously 4 ml per hour for first 24 hour after surgery. Pain Score, Sedation Score, Blood pressure and heart rate, Nausea and Vomiting and use of additional analgesia evaluated at the PACU and 4, 6, 12, 24 hours after surgery. Pain assessed by Visual Analogue Score (0= no pain, 10= the worst imaginable pain). The demographic characteristics of the two groups data of study recorded on common questionnaire form and data sheet. After that, data analysis planned after completion of the trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012103011319N1**

Registration date: **2012-12-08, 1391/09/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-08, 1391/09/18

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Deputy, Tehran University of Medical Sciences (TUMS)

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of paracetamol and ketamine for post-operative pain management in patients undergoing total abdominal hysterectomy

Public title

Comparison of paracetamol and ketamine for post-operative pain management in patients undergoing total abdominal hysterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 1-Volunteers ages between 25-65; 2- American Society of Anesthesiologist class (ASA) I, II Physical Status; 3- Scheduled for total abdominal hysterectomy surgery; 4- Written informed consent , based on Tehran University Medical Sciences , Ethical Committee Approved Study design. Exclusion Criteria: 1-Out of 25-65 ages limitations; 2- Addiction to opiates; 3- Known allergy to acetaminophen or ketamine; 4- History of alcoholism and drug abuse; 5- History of hepatic disease; 6- Dispensing of patient any time after informed consent or lack of patient consent; 7- History of seizure

Age

From **25 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences (TUMS)

Street address

Poursina St, Tehran

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Tehran

Postal code

1445613131

Approval date

2012-11-20, 1391/08/30

Ethics committee reference number

130/2035/91/3

Health conditions studied

1

Description of health condition studied

Post operative analgesia after total abdominal hysterectomy

ICD-10 code

Z90.710

ICD-10 code description

Acquired absence of uterus

Primary outcomes

1

Description

Pain

Timepoint

At recovery room, 4, 6, 12 and 24 o'clock after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

The patients will evaluate for Sedation, Nausea and Vomiting, additional requirement for analgesia and probable complication during study includes of: pruritus and other complication in both groups.

Timepoint

At recovery room, 4, 6, 12 and 24 o'clock after surgery

Method of measurement

Score of sedation and nausea and vomiting type and dosage of additional analgesic

Intervention groups

1

Description

Apotel in case group

Category

Treatment - Drugs

2

Description

Ketamine in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-Akram Medical Center

Full name of responsible person

Hamid Reza Feiz M.D

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Full name of responsible person

Dr Fotouhi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Research Deputy, Tehran University of Medical Sciences
(TUMS)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

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Position

Assistant professor of anesthesiology

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>